

complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

#### TCT-515

### THE MULTILAYER FLOW MODULATOR STENT FOR THE TREATMENT OF THORACO ABDOMINAL AND ABDOMINAL AORTIC ANEURYSMS. MOROCCAN EXPERIENCE

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**Background:** Thoraco Abdominal Aortic Aneurysms (TAAA) and Abdominal Aortic Aneurysms (AAA) are traditionally treated surgically, but more and more by interventional procedures (endografts, fenestrated, branched grafts, chimney techniques). We used a new concept of stent, the Multilayer Stent Flow Modulator (M.F.M) to treat these aneurysms (A) and try to avoid some major complications.

**Methods:** This selfexpandable M.F.M is a 3 D braided tube made of several interconnected layers without any covering. We will explain and demonstrate the key principles of the stent leading to thrombosis, shrinkage of the A, eliminating the risk of rupture. Moreover, this M.F.M preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels...).

**Results:** 10 TAAA, 8 AAA (7 extended to both iliac arteries) treated with MFM in very high risk patients. 53 MFM implanted (1 to 5 per pt). o Technical success: 100% o At 30 days: no neurological complication, branch patency 100%, no death o During the follow up we had 3 deaths not device related. CT scan control performed at 1, 3, 6, 12, 18 months with calculation of A. Diameters and Volumes. o All collateral branches remain patent and we observed a progressive thrombosis and shrinkage of the aneurysmal sac depending on the size of the collaterals. Some patients developed a thrombus after 1 month, some after 6 months and some even after 18 months. A significant mean diameter reduction was observed between baseline and 6 months: 17,25 mm reduction for the transversal diameter, 13,83 mm for the antero posterior diameter in the TAAA group. Overtime the ratio thrombus volume / Total Volume is increasing and the ratio Residual Flow Volume / Total Volume is decreasing. The problems of thrombosis, shrinkage and volume reduction of the aneurysmal sac will be discussed. The complications rates with M.F.M appear lower in comparison with current endovascular techniques, and with surgery.

**Conclusions:** The M.F.M represents an alternative to current devices to treat TAAA and AAA. It is a safe procedure with a low complication rate. The first results are promising. A larger study is ongoing.

#### TCT-516

### Argatroban and t-PA During Catheter-Directed thrombolysis for Extensive lower Extremity Deep Venous Thrombosis

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**Background:** Extensive acute deep venous thrombosis (DVT) responds favorably to catheter directed thrombolysis (CDT). Argatroban is an effective parenteral direct thrombin inhibitor which makes it an attractive drug for DVT treatment. There is a paucity of data on the utilization of argatroban in combination with tPA for extensive DVT.

**Methods:** 35 patients with extensive DVT involving the femoropopliteal and iliac veins underwent PEVI. DVT was bilateral in 24 patients. A 6-8 F sheath was placed in each popliteal vein under ultrasound guidance. DVT had developed within 10 days of major surgery in 7 patients. For maceration of the clot balloon venoplasty was performed in all. Subsequently an infusion catheter was placed through the popliteal sheath(s) and tPA delivered at 1mg/hr for 20-24 hours for unilateral DVT and at 0.75 mg/hr through each infusion catheter for bilateral involvement. For unilateral DVT, argatroban was given at 0.5 -1 mcg/kg/min through the side port of the sheath and for bilateral DVT it was given at 0.3- 0.75 mcg/kg/min. PTT was kept between 50-90 seconds. Every 3 hours the PTT was checked if there was a change in the Argatroban dose. It was checked every 12 hours if the PTT had remained within the therapeutic range. Follow-up venography was performed between 20- 30 hours after PEVI.

**Results:** With the above regimen there were no bleeding complications even in the 7 patients with recent surgery. Complete or significant resolution of thrombus was noted in 32patients (91%). In 3 patients who previously had occlusive thrombus within their IVC filter, the iliac and femoropopliteal DVT had resolved, however some degree of thrombus in the IVC filter persisted. These were treated with further thrombectomy and the procedure terminated at that time with removal of the sheaths.

**Conclusions:** CDT using a combination of low dose argatroban and tPA is highly effective and safe in the treatment of massive diffuse DVT. The unacceptably high rates of bleeding previously reported are not applicable to the contemporary era. A synergistic effect exists between argatroban and tPA which make them an ideal anticoagulant- thrombolytic combination for CDT.

#### TCT-517

### Reduction of Hospitalization and Duration of Anticoagulation for Deep Venous Thrombosis in Patients Undergoing Percutaneous Endovenous Intervention and Receiving Novel Anticoagulants

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**Background:** The current recommendation for the treatment of deep venous thrombosis (DVT) is at least 5 days of parenteral anticoagulation with a minimum of 24 hours of overlap with a vitamin K antagonist at a therapeutic INR. It has been well established that percutaneous endovenous intervention (PEVI) reduces the sequelae of DVT by early removal of thrombus. The efficacy and safety of novel anticoagulants rivaroxaban and dabigatran following PEVI has not been investigated.

**Methods:** 93 patients with femoropopliteal, iliac, upper extremity and internal jugular DVT who had undergone PEVI underwent initiation of dabigatran (34 patients) or rivaroxaban (59 patients) within 2 hours after their procedure. No parenteral anticoagulation was given when oral anticoagulants were started. The mean follow up was 18±3 months. Aspirin at 81mg daily was given to 18 patients who had received an endovenous stent and was continued for 1 month. The patients were evaluated for recurrent venous thromboembolic (VTE) disease and bleeding during the follow- up period.

**Results:** There was no bleeding or recurrent VTE in any patient. Two patients could not tolerate dabigatran due to gastrointestinal side effects. The mean duration of parenteral treatment was 31±5 hours. Enoxaparin was the parenteral anticoagulant in 32 patients and unfractionated heparin in the remainder. The mean duration of hospitalization was 29±5 hours. At follow-up 3 patients died due to cancer.

**Conclusions:** In patients undergoing PEVI, the duration of safe and effective parenteral anticoagulation is less than the traditionally accepted minimum of 5 days. Initiation of rivaroxaban or dabigatran soon after PEVI promotes early discharge and obviates the inconveniences associated with regulation of INR.

#### TCT-518

### One-Year Results of the Multi-layer Flow Modulator Stent in the Management of Thoracoabdominal Aortic Aneurysms.

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**Background:** We present the first 55 cases of MFM implanted under indication for use to treat aortic disease. All were done on compassionate basis, in 11 countries. Primary Endpoints are Freedom from Rupture and Aneurysm-related Death.

**Methods:** They were 31 Crawford Thoraco-abdominal (8 Type I, 3 Type II, 9 Type III, and 11 Type IV), 7 arch, 3 abdominal, 8 suprarenal aortic aneurysms and 6 type B dissections. Mean age of 64.5 years +/- 18years; mean aneurysm diameter was 6.04cm+/-1.66cm (Median 5.76cm). Mean number of side branches covered was 3.7 per case (median 4, range 0-6). Total 108 stents used, mean of 1.96 MFM per case.(Median 2, range 1-5)

**Results:** One-year Aneurysm-related survival was 93.7% (SE+/-4.44%). No rupture occurred. Technical success was 98.2%. One-year all-cause survival was 84.8% (SE+/-6.25%). There was no paraplegia. No peri-operative visceral insult. At 12 months all 202 side branches were patent. No stent fractures. One-year intervention-free survival was 92.4% (SE+/-5.09%) At six months mean rate of sac volume increase was 0.36% per month. At twelve months the rate of increase had slowed to 0.28% per month. The ratio of thrombus to total volume stayed almost constant over the 12 months at 0.48, while the ratio of flow to total volume fell from 0.21 to 0.12 at 12 months.

**Conclusions:** Increasing sac size did not herald rupture. MFM implantation instigates a process of aortic remodeling involving initial thrombus deposition, which slowed between six and twelve months. The MFM was not associated with loss of native side branches.

#### TCT-519

### Comparison of Wound Healing in Critical Limb Ischemia according to Wound Types with and without Successful Revascularization

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**Background:** To achieve successful revascularization is important for wound healing in critical limb ischemia (CLI) with tissue loss following endovascular therapy (EVT). However, we sometimes experience failure to achieve wound healing even after successful EVT. We investigated the relationship between wound healing and successful revascularization according to wound types.

**Methods:** Between April 2007 and April 2012, 171 CLI patients (204 limbs) classified to Rutherford 5 or 6 were treated by EVT in our institute. In these limbs, 199 individual wounds exited on foot and were evaluated wound healing rates and time to healing according to their wound types with and without successful revascularization. Wound types were divided into three groups, group T (Toe wound, n=128), group H

(Heel wound, n=28), and group E (Extensive wound extending onto the forefoot or midfoot along with dorsum or plantar surfaces, n=43). Successful revascularization was defined as achievement of direct blood flow to the wounds evaluated by digital subtraction angiography just after EVT.

**Results:** We achieved successful revascularization 73% in group T, 79% in group H, and 51% in group E. In success group, wound healing rates were 81% in group T, 59% in group H, and 32% in group E ( $p < 0.001$ ). On the other hand, in non-success group, wound healing rates were 53% in group T, 33% in group H, and 0% in group E ( $p < 0.001$ ). Time to healing were 50 days (interquartile range: 23-99 days), and 65 days (28-156 days) in group T ( $p = 0.20$ ); 145 days (121-317 days), and 260 days (234-285 days) in group H ( $p = 0.39$ ) with and without successful revascularization.

**Conclusions:** Successful revascularization increased wound healing rates of all types wounds, however, time to healing was not statistically different with and without successful revascularization. Not only successful revascularization but also various factors are associated with wound healing in patients with CLI.

## TCT-520

### Long-Term CT-Scan Follow-up Of Inferior Vena Cava Filter: Warning Bells From A Single-Center Experience

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**Background:** Inferior vena cava filters (IVCF) have increasingly been used for prevention of pulmonary thromboembolism (PTE) in deep venous thrombosis (DVT) when anticoagulant therapy is contraindicated or in patients presumed to be at high risk. Persistent DVT and risk factors or lack of follow-up may account for IVCF left permanently in place. We assessed long-term performance of permanent IVCF with abdominal CT scan.

**Methods:** ALN IVCF (ALN Implants Chirurgicaux®) is a retrievable, non-magnetic, stainless steel filter consisting of nine legs. Six short legs (SL) provide anchorage and three long legs (LL) allow coaxial filter positioning. Among 54 pts with DVT who received ALN IVCF, 12 pts (58% female, mean age 55 years, range 19-80) with filter left permanently in place underwent abdomen CT scan during follow-up. Six pts had a second CT scan and one pt had four CT scans. Time from IVCF implantation to CT scan follow-up ranged from 2 to 163 (mean 60) months. Penetration of filter into the IVC wall was defined as  $\geq 3$  mm protrusion of a leg outside the IVC wall. Grade 3 penetration was defined as any interaction with an adjacent organ outside the IVC. Fracture was defined as any loss in structural integrity of the IVCF. Embolization was defined as remote endovascular migration of a fractured leg.

**Results:** In all pts (12/12), CT scan showed penetration of filter legs. Overall, 57/72 (79%) of the SL but only 1/32 (3%) of the LL were outside IVC wall. Grade 3 penetration of 13 (18%) SL was observed in 8(67%) pts: 9 into a vertebral body and 4 into small intestine. In 4 (33%) pts, 11 (15%) SL fractures were observed, while in 3 (25%) pts embolization of a total of 7 SL occurred: 3 in a pulmonary artery branch, 2 in the right side of the heart, 1 in the liver and 1 whose embolization site was not found. None of the pts had clinical manifestations related to IVCF dysfunction.

**Conclusions:** IVC injury and loss of IVCF structural integrity seem to be the rule rather than the exception after prolonged IVCF positioning. These findings should encourage IVCF removal when possible. Furthermore, surveillance follow-up with abdominal X-ray or CT scan in all patients with permanent IVCF is strongly advisable.

## TCT-521

### Comparison of Clinical Outcomes of Endovascular Intervention between Octogenarians and Non-Octogenarians with Peripheral Arterial Diseases

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**Background:** To compare clinical outcomes of endovascular intervention (EVI) between octogenarians and non-octogenarians with peripheral arterial disease (PAD)

**Methods:** A retrospective analysis of 490 consecutive patients (619 legs) who underwent EVI between June 2005 and February 2013, was conducted in a prospectively maintained database. Patients  $\geq 80$  (128 patients, 158 limbs) and  $< 80$  years old (362 patients, 461 limbs) were compared to demographics, 30-day major adverse vascular events (MACE), limb salvage, sustained clinical success (SCS), secondary sustained clinical success (SSCS) and overall survival.

**Results:** Patients  $\geq 80$  were more likely to be female and have more atrial fibrillation, whereas those  $< 80$  were more likely to have diabetes mellitus, dialysis dependence, hyperlipidemia, high body mass index and claudicants. There were more multi-level interventions in patients  $\geq 80$  (55% vs. 45%,  $p=0.04$ ). The procedure success rate (93.7% vs. 94%,  $p=1.0$ ) and 30-day MACE were similar in both age groups (10.1% vs. 9.3%,  $p=1.0$ ). The SCS ( $<80$  vs.  $\geq 80$ , 56% vs. 53%,  $p=0.859$ ), SSCS ( $<80$  vs.  $\geq 80$ , 72% vs. 76%,  $p=0.07$ ) and limb salvage rates ( $<80$  vs.  $\geq 80$ , 91% vs. 95%,  $p=0.085$ ) were

similar between both age groups at 24 months. Patients  $\geq 80$  still have shorter survival as compared to those  $<80$  (57% vs. 71%,  $p<0.01$ ) during the follow-up period.

**Conclusions:** Our results suggest EVI in octogenarian with more complex lesions is safe and feasible without increasing the risk of complications. Although the overall survival remained worse in this elderly group, 24-month SCS, SSCS and limb salvage rate were similar in both age group. For patients  $\geq 80$  with PAD, EVI should be considered as first-line treatment of choice.

## TCT-522

### The impact of statin therapy for atherosclerotic renal artery stenosis after percutaneous transluminal renal artery stenting

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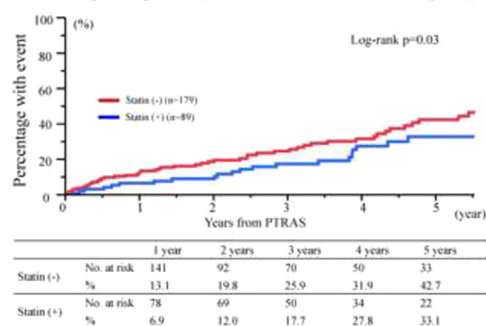
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**Background:** Although percutaneous transluminal renal artery stenting (PTRAS) has become popular for treating atherosclerotic renal artery stenosis (ARAS), effect of statin after PTRAS remains uncertain. The aim of this study is to examine the influence of statin after PTRAS.

**Methods:** Consecutive 268 patients who were diagnosed as atherosclerotic renal artery stenosis by duplex ultrasound and angiography received renal artery stenting, and they were enrolled in the study between Aug 1996 and July 2010. Data were collected on clinical outcomes over a mean follow-up period of  $43 \pm 30$  months. The primary endpoint was defined as the composite of all-cause death, hospitalization of heart failure, and initiation of dialysis.

**Results:** 89 patients (33%) received statin treatment during follow-up period. According to Kaplan-Meier analysis, the log-rank test showed patients who received statin treatment have a lower event rate than patients without statin (Log-rank test;  $p=0.03$ ), and percentage with event was reduced by 10% in the patients with statin treatment 5 years after PTRAS.

### Primary endpoint (Death, heart failure, dialysis)



**Conclusions:** In conclusion, statin therapy was associated with a better outcome in patients with atherosclerotic renal artery stenosis who were received PTRAS.

## TCT-523

### Multicenter Registry for Peripheral Arterial Disease Interventions and Outcomes (XLPAD Registry)

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**Background:** There are limited data regarding contemporary use and comparative clinical outcomes of stent and non-stent based revascularization of infra-inguinal peripheral arterial vessels.